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8484 Westpark Drive, 9th Floor, McLean, VA 22102 (US).

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(71) Applicant: ADVANCED STENT TECHNOLOGIES, INC. [US/US]; 6900 Koll Center Parkway, Suite 415, Pleasanton, CA 94566 (US).

(71) Applicants and

(72) Inventors: WILLIAMS, Eric [US/US]; 2068 Davis Drive, Fairfield, CA 94533 (US). MIRZAAE, Daryush [US/US]; 629 Ashbourne Drive, Sunnyvale, CA 94087 (US). KHENANSHO, Michael [US/US]; 4205 Laguna Seca Court, Modesto, CA 95358 (US). SCHWARTZ, Michael, [US/US]; 400 Beale Street, #308, San Francisco, CA 94105 (US).

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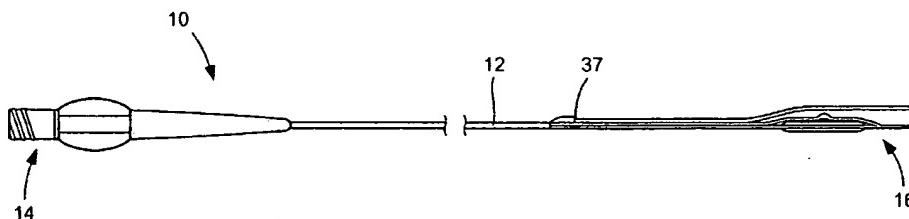
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(54) Title: CATHETER BALLOON SYSTEMS AND METHODS

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(57) Abstract: An apparatus for treatment of a bifurcation of a body lumen, the bifurcation having a main vessel and a branch vessel, the apparatus includes a bifurcated balloon with a first branch portion and a second branch portion, the second branch portion including an inflatable portion adapted to extend toward the branch vessel, the bifurcated balloon also having a proximal shaft portion and a distal shaft portion connected to the inflatable portion of the second branch portion, and wherein the first branch portion and the second branch portion each have a longitudinal axis, the axis of the first branch portion being substantially parallel to the longitudinal axis of the second branch portion.

## CATHETER BALLOON SYSTEMS AND METHODS

### CROSS REFERENCE TO RELATED APPLICATIONS

Pursuant to 35 U.S.C. § 1.19(e), this application claims the benefit of priority of U.S. Provisional Application No. 60/488,006 filed July 18, 2003; U.S. Provisional Application No. 60/518,870 filed November 12, 2003; U.S. Provisional Application No. 60/547,778 filed February 27, 2004; and U.S. Provisional Application No. 60/548,868 filed March 2, 2004. The complete disclosures of the above-referenced applications are incorporated herein by reference.

### FIELD OF THE INVENTION

The present invention relates to the field of medical balloon catheters and, more particularly, to systems for delivering a stent at or near a bifurcation of a body lumen.

### BACKGROUND OF THE INVENTION

Balloon catheters, with or without stents, are used to treat strictures, stenoses, or narrowings in various parts of the human body. Devices of numerous designs have been utilized for angioplasty, stents and grafts or combination stent/grafts. Varied catheter designs have been developed for the dilatation of stenoses and to deliver prostheses to treatment sites within the body lumen.

Illustrative procedures involving balloon catheters include percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA), which may be used to reduce arterial build-up such as caused by the accumulation of atherosclerotic plaque. These procedures involve passing a balloon catheter over a guidewire to a stenosis with the aid of a guide catheter. The guidewire extends from a remote incision to the site of the stenosis, and typically across the lesion. The balloon catheter is passed over the guidewire, and ultimately positioned across the lesion.

Once the balloon catheter is positioned appropriately across the lesion, (e.g., under fluoroscopic guidance), the balloon is inflated, which breaks the plaque of the stenosis and causes the arterial cross section to increase. Then the balloon is deflated and

withdrawn over the guidewire into the guide catheter, and from the body of the patient.

In many cases, a stent or other prosthesis must be implanted to provide support for the artery. When such a device is to be implanted, a balloon catheter which carries a stent on its balloon is deployed at the site of the stenosis. The balloon and accompanying prosthesis are positioned at the location of the stenosis, and the balloon is inflated to circumferentially expand and thereby implant the prosthesis. Thereafter, the balloon is deflated and the catheter and the guidewire are withdrawn from the patient.

Administering PTCA and/or implanting a stent at a bifurcation in a body lumen poses further challenges for the effective treatment of stenoses in the lumen. For example, dilating a main vessel at a bifurcation may cause narrowing of the adjacent branch vessel. In response to such a challenge, attempts to simultaneously dilate both branches of the bifurcated vessel have been pursued. These attempts include deploying more than one balloon, more than one prosthesis, a bifurcated prosthesis, or some combination of the foregoing. However, simultaneously deploying multiple and/or bifurcated balloons with or without endoluminal prostheses, hereinafter individually and collectively referred to as a bifurcated assembly, requires accurate placement of the assembly. Deploying multiple stents requires positioning a main body within the main vessel adjacent the bifurcation, and then attempting to position another stent separately into the branch vessel of the body lumen. Alternatives to that include deploying a dedicated bifurcated stent including a tubular body or trunk and two tubular legs extending from the trunk. Examples of bifurcated stents are shown in U.S. Patent No. 5,723,004 to Dereume et al., U.S. Patent No. 4,994,071 to MacGregor, and U.S. Patent No. 5,755,734 to Richter et al.

Additional bifurcation stent delivery systems that provide improved reliable treatment at bifurcations are disclosed, for example, in U.S. Patent No. 6,325,826 to Vardi et al. and U.S. Patent No. 6,210,429 to Vardi et al. The contents of these aforementioned patents are incorporated herein by reference.

A need still exists for further improved devices and techniques for treating a bifurcated body lumen. For example, a need further exists for additional stent

delivery systems that can be used with stents having a branch access side hole and/or an extendible branch portion.

#### SUMMARY OF THE INVENTION

The present invention is directed to devices and techniques for treating a bifurcated body lumen including systems for delivering an endoluminal prosthesis at or near a bifurcation of a body lumen. Systems, devices and techniques are disclosed comprising balloon catheters configured to successfully and reliably deploy stents at a bifurcation in a body lumen. Additionally, the balloon catheters can be employed as balloon angioplasty catheters to treat occlusions in blood vessels such as for instance in percutaneous transluminal coronary angioplasty (PTCA) procedures.

According to one aspect, the present invention provides an apparatus for treatment of a bifurcation of a body lumen, the bifurcation comprising a main vessel and a branch vessel, the apparatus comprising: a bifurcated balloon comprising a first branch portion and a second branch portion; the second branch portion comprising an inflatable portion adapted to extend toward the branch vessel, the balloon further comprising a proximal shaft portion and a distal shaft portion connected to the inflatable portion.

According to another aspect, the present invention provides a system for treatment of a bifurcated body lumen, the system comprising: a catheter for insertion into said body lumen, the catheter having a bifurcated distal end comprising first and second branches; and a bifurcated balloon positioned on one of said first and second branches; the balloon having a first balloon branch portion and a second balloon branch portion, the first balloon branch portion including a first inflatable portion and the second balloon branch portion including a second inflatable portion, and wherein the first inflatable portion has a generally cylindrical shape when inflated and the second inflatable portion has a generally offset bulbous shape when inflated.

According to yet another aspect, the present invention provides a method of treating a bifurcation of a body lumen, the bifurcation comprising a main vessel and a branch vessel, the method comprising: (i) introducing a bifurcated balloon and stent assembly into the main branch, the bifurcated balloon comprising at least one inflatable portion; (ii) positioning the assembly at the bifurcation; (iii) inflating the

bifurcated balloon thereby expanding the inflatable portion and the stent toward the branch vessel.

According to a further aspect, the present invention provides a balloon catheter, comprising: a catheter having a distal end, a proximal end and an inflation lumen; a balloon formed on the distal end of the catheter, the balloon being in fluid communication with the inflation lumen and being capable of being expanded from an unexpanded configuration to an expanded configuration, wherein the balloon has a herniation in the expanded configuration.

According to still another aspect, the present invention provides a herniated balloon catheter, comprising: a balloon constructed from a composite material and including a woven material formed with a herniation, wherein the balloon has a herniation in the expanded condition.

According to a further aspect, the present invention provides a stent delivery system, comprising: a catheter having a balloon with a herniation; and a stent having an opening including an outwardly expandable portion, the stent being disposed on the balloon with the stent opening aligned with the herniation, whereby upon expansion of the balloon the herniation expands causing the outwardly expandable portion of the stent to extend toward the branch vessel.

According to another aspect, the present invention provides a method for treating a bifurcated vessel, the method comprising: introducing into a vessel a catheter having a distal end, a proximal end, and a guide wire lumen that is adapted to receive a guide wire, a balloon having a distal end and a proximal end, the balloon being disposed near the distal end of the catheter, the balloon having a protrusion at a location between the distal end and proximal end of the balloon, and a stent having a side opening through a wall thereof, the stent being disposed over the balloon, wherein the protrusion of the balloon is positioned through the side opening; positioning the catheter at a bifurcation by aligning the protrusion with a side branch vessel; and expanding the balloon so as to expand the stent such that the side opening is aligned with the opening of the bifurcated vessel.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented to provide what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention.

FIG. 1 is a side view of an illustrative embodiment of a stent delivery system constructed in accordance with the present invention.

FIG. 2 is an enlarged side view taken of the distal portion of the system of FIG. 1.

FIG. 3 is a view of the stent delivery system of FIG. 1 in a blood vessel shown approaching a bifurcation in the vessel without a stent mounted thereon in accordance with a method of the present invention.

FIG. 4 is a view of the system of FIG. 3, including a stent mounted thereon.

FIG. 5 is a view of the stent delivery system of FIG. 1 in a blood vessel located at a bifurcation in the vessel without a stent mounted thereon in accordance with a method of the present invention.

FIG. 6 is a cross-sectional side view of the stent delivery system of FIG. 1 with a stent mounted thereon and shown in the expanded condition.

FIG. 7 is a perspective view of a balloon configured according to one embodiment of the present invention.

FIG. 8 is a perspective view of a balloon constructed according to an alternative embodiment of the present invention.

FIG. 9 is a perspective view of a balloon configured according to a further embodiment of the present invention.

FIG. 10 is a perspective view of a balloon configured according to yet another alternative embodiment of the present invention.

FIG. 11 is a perspective view of a balloon configured according to another embodiment of the present invention.

FIG. 12 is a perspective view of a balloon catheter configured according to another embodiment of the present invention.

FIG. 13 is a perspective view of a portion of a balloon constructed according to the principles of the embodiment of FIG. 11.

FIG. 14 is a perspective view of a portion of a balloon constructed according to an alternative embodiment of the present invention.

FIG. 15 is a side view of the balloon of FIG. 13 shown in an unexpanded state.

FIG. 16 is a cross-sectional view of an alternative embodiment of a balloon in an expanded state constructed according the principles of the present invention.

FIG.17 is a cross-sectional view of an alternative embodiment of a balloon constructed in accordance with the present invention.

FIG.18 is a cross-sectional view of yet another alternative embodiment of a balloon constructed in accordance with the present invention.

FIG. 19 is a cross-sectional view of yet another alternative embodiment of a balloon constructed in accordance with the present invention.

FIG. 20 is a cross-sectional view of still another embodiment of an alternative balloon construction formed according to the principles of the present invention.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to balloon catheters such as balloon angioplasty catheters to treat occlusions in blood vessels. The balloon catheters can be used alone or with a stent, prosthesis or graft. Such a stent delivery system can be used for placement of a stent in a body lumen, particularly at vessel bifurcations. A preferred stent to be delivered is generally configured to at least partially cover a portion of a branch vessel as well as a main vessel. In general, a wide variety of stents and deployment methods may be used with the stent delivery system embodiments of the

present invention and the present invention should be understood to not be limited to any particular stent design or configuration. Examples of the types of stents that may be used with the delivery systems of the present invention are disclosed, for example, in U.S. Patent No. 6,210,429 to Vardi et al., U.S. Patent No. 6,325,826 to Vardi et al., and co-pending U.S. Patent Application No. 10/644,550, entitled "Stent With a Protruding Branch Portion For Bifurcated Vessels," the entire contents of which are incorporated herein by reference. In general, the aforementioned stent includes a branch portion located at some point along the length of the stent that is configured to be extendible into a branch vessel in a vessel bifurcation. Once the stent is in position in the main vessel and the branch portion is aligned with the side branch vessel the stent can be expanded and the delivery system is particularly adapted to expand the stent branch portion into the side branch vessel. The stent, including the branch portion, may be expanded with a single expansion or multiple expansions.

An illustrative view of one embodiment of a stent delivery system **10** constructed in accordance with the present invention is shown in FIG. 1. Stent delivery system **10** generally comprises an elongate main catheter shaft **12** extending from a proximal end **14** to a distal end **16**. As best seen in FIG. 2, distal end **16** has a bifurcated tip structure with two branch portions, a main vessel branch portion **18** and a side branch sheath **20** that branch off of main catheter shaft **12**. A bifurcated balloon **26** is attached to main vessel branch portion **18** adjacent the distal end **16** and comprises first and second branch portions **27, 30**. First branch portion **27** of balloon **26** comprises an elongate inflatable portion **28**. Second branch portion **30** of balloon **26** comprises a second inflatable portion or auxiliary inflatable portion **32**. Second branch portion **30** includes an inflation lumen that branches off from first branch portion **27** proximally from the balloon **26** and extends substantially adjacent elongate inflatable portion **28**. The distal end of second branch portion **30** is attached to first branch portion **27** at a location distally from the balloon **26**. In one preferred embodiment, the distal end of branch portion **30** is fixedly attached distally of balloon **26** in order to prevent at least the second inflatable portion **32** from moving around the first branch portion **27**, although in alternate embodiments it may be removably attached.

In a preferred embodiment, first inflatable portion 28 is generally cylindrical and extends coaxially along main vessel branch portion 18. Second inflatable portion 32 may have a shape and size adapted to extend into the branch vessel as shown and described herein. For example, portion 32 may have a generally offset configuration and may be positioned adjacent or in abutting relation with respect to elongate inflatable portion 28.

The first and second inflatable portions can have varied shapes, sizes and positioning in accordance with the principles of the invention. For example, in alternative design variations, accurate sizing and positioning of the inflatable portions relative to the vessel may be achieved.

According to the present invention, the inflatable portions, or balloons, can be constructed of any suitable material. For example, the balloons may be constructed of an appropriate polymeric material. Particular examples include the polyamide family, or the polyamide blend family, polyethylene (PE), polyethylene terephthalate (PET), polyurethanes, polyamides, and polyamide blends such as PBAX. The compliance of the first inflatable portion 28 and the second inflatable portion 32 can be the same or different. In one preferred embodiment, second inflatable portion 32 is longitudinally positioned at a generally central location relative to the first inflatable portion 28. In alternate embodiments, second inflatable portion 32 may be positioned at any position adjacent first inflatable portion 28.

In a preferred embodiment, balloon branch portions 27 and 30 have a common inflation lumen 34. Inflation lumen 34 can be conventional, and extend from a portion of the stent delivery system which always remains outside of the patient (not pictured). Inflation lumen 34 extends distally into each of first and second branch portions 27 and 30 and thus, inflation lumen 34 is in fluid communication with the interiors of first inflatable portion 28 and second inflatable portion 32. Thus inflation lumen 34 is used to supply pressurized inflation fluid to first inflatable portion 28 and second inflatable portion 32 when it is desired to inflate balloon 26. Inflation lumen 34 is also used to drain inflation fluid from first inflatable portion 28 and second inflatable portion 32 when it is desired to deflate the balloon. First and second inflatable portions are initially deflated when directing the stent delivery device to the bifurcation lesion in a patient. In this embodiment, the inflation lumen 34 inflates

inflatable portions 28, 32 substantially simultaneously. In an alternative embodiment, branch balloon portions 27 and 30 have separate inflation lumens. In this alternative embodiment inflatable portions 28 and 32 can be inflated simultaneously or sequentially. When sequential inflation is desired, preferably, the first inflatable portion 28 is inflated first, followed by the inflation of the second portion 32.

First main guidewire lumen 22 extends through main vessel branch portion 18 and first inflatable portion 28. Although first guidewire lumen 22 extends through first inflatable portion 28 in the embodiment depicted in FIGS. 1-2, it is distinct from inflation lumen 34 and is not in fluid communication with the interior of balloon 26 as shown. Preferably, the first guidewire lumen 22 extends distally of first inflatable portion 28 and has an open distal end. Alternatively, guidewire lumen 22 can extend through branch portion 30.

In the embodiment depicted in FIGS. 1-2, an optional side sheath 20 is illustrated which does not include an inflatable balloon. Although in alternate embodiments side sheath 20 could include an inflatable portion, as described for example in co-pending U.S. Patent Application No. 10/644,550 entitled "Stent With a Protruding Branch Portion For Bifurcated Vessels". Side sheath 20 is exterior to and distinct from inflation lumen 34 and thus is also not in fluid communication with the interior of balloon 26 as shown. As shown in the embodiment of FIGS. 1-2, side sheath 20 preferably extends distally of balloon 26, and may include a proximal open end 37 at any point along the length of the stent delivery system and a distal open end 39. Side sheath 20 can be of the type as described in U.S. Patent No. 6,325,826 to Vardi, *et al.*, for example, and in operation the side sheath 20 can extend through a branch access hole of the stent.

With reference to FIGS. 3-6, an exemplary manner of practicing the invention will now be discussed. Referring to FIGS. 3 and 5, the delivery system is shown in relation to an exemplary body lumen adjacent a blood vessel bifurcation 40 usually comprised of plaque and the delivery system 10 is shown without a stent mounted thereon (FIGS. 3 and 5). Figs. 4 and 6 show the stent delivery system 10 with a stent 50 mounted thereon.

Bifurcation 40 includes a main vessel 42 and a branch vessel 44. Illustrative obstructions 46 located within bifurcation 40 may span or at least partially obstruct main vessel 42 and a proximal portion branch vessel 44. Generally, stent delivery system 10 may be threaded over a first main guidewire placed in the main vessel to guide the delivery system to the treatment site. More specifically, the proximal end of first guidewire 36 is threaded into the distal open end of the main guidewire lumen 22 and the delivery system is tracked to a position at or near bifurcation 40, as depicted in FIG. 3. Second guidewire 38 (FIG. 5) is then threaded into stent delivery system 10 from the proximal end of the delivery system. More specifically, second guidewire 38 is threaded into the open proximal end 37 of side sheath 20, and may extend therefrom through the open distal end 39 of side sheath 20, as depicted in FIG. 5. Alternatively, second guidewire 38 can be resting dormant on the inside of the side sheath, and when the system is proximal the bifurcation 40, it can be advanced out of side sheath 20 into side branch vessel 44. The systems in accordance with the principles of the invention may be used in over-the-wire or rapid exchange systems, which may include rapid exchange on either or both of the side sheath or main catheter. Rapid exchange is described in one exemplary embodiment in US2003/0181923 to Vardi et al., published September 25, 2003, the entire contents of which are incorporated herein by reference.

In one embodiment, the stent delivery system 10 is positioned near bifurcation 40, and with the distal end 16 (FIG. 1) positioned near side branch vessel 44 (FIGS. 3-6), second guidewire 38 is advanced into side branch vessel 44 from side sheath 20. Then, the first and second inflatable portions of balloon 26 are positioned adjacent the opening of side branch vessel 44 such that auxiliary inflatable side portion 32 of bifurcated balloon 26 is aligned with side branch vessel. In one exemplary embodiment, alignment may be achieved using markers, as described in U.S. Patent No. 6,692,483 to Vardi, et al., the entire contents of which is incorporated herein by reference. Second guidewire 38 remains in side branch sheath 20, and the distal end 16 of system 10 remains in main vessel 42. First guidewire 36 remains within first guidewire lumen 22, and may be further advanced and positioned in main branch vessel 42.

Once the system is properly positioned, pressurized fluid is supplied to first and second inflatable portions 28 and 32, respectively, of balloon 26 to dilate the body lumen and expand a stent mounted thereon (FIG. 6). Preferably, the inflatable portion 28 expands the main body of the stent and inflatable portion 32 expands the side (opening) and expandable branch structure of the stent, as discussed in more detail with reference to FIG. 6. After inflatable portions 28 and 32 have been inflated as described above, balloon 26 is deflated by draining the inflation fluid via inflation lumen 34. This allows the inflatable portions 28 and 32 to collapse in preparation for withdrawal of the assembly from vessel 42.

Referring now to FIGS. 4 and 6, one preferred embodiment is shown with stent delivery system 10 and an exemplary stent 50 mounted on the exterior of distal end 16 of the stent delivery system. Stent 50 includes an extendible branch portion 52 configured to extend into a branch vessel as discussed in co-pending U.S. Application No. 10/644,550, entitled "Stent with Protruding Branch Portion for Bifurcated Vessels". The second inflatable portion 32 may be configured and positioned to deploy the outwardly expanding stent elements or branch portion 52 and may be positioned adjacent to the branch portion 52, or into a side branch access opening in the stent. As shown in FIG. 6, when first and second inflatable portions 28 and 32 are expanded, they simultaneously or sequentially, depending upon the configuration of the inflation lumen, cause the stent 50 to expand in the main vessel 42 and the branch portion 52 of stent 50 to be pushed or extended into the branch vessel 44. Upon inflation of the balloon 26, the second inflatable portion 32 expands and extends the branch portion 52 toward the branch vessel to open and support the entrance or ostium of the side branch artery. This would occur simultaneously when the balloons share a common inflation lumen but could be sequentially if separate inflation lumens are used. Although a bifurcated balloon is depicted, as shown, more than two inflatable portions or more than two balloons may be utilized with the present invention.

As illustrated, for example, in FIGS. 5 and 6, the first and second branch portions 27 and 30 have a longitudinal axis A. The longitudinal axes are substantially parallel with each other. The term "substantially parallel" is intended to encompass deviations from a purely parallel relationship which may be caused by flexure of the

branch portions 27 and 30, or other components, experienced during insertion, travel, and deployment within a body lumen.

FIG. 7 is an enlarged perspective view of the auxiliary inflatable side portion 32 of bifurcated balloon 26, which is referred to in the previous embodiments depicted in FIGS. 1-6. According to this embodiment, the central portion 33 of the auxiliary inflatable side portion 32 extends in a generally equidistant manner from the longitudinal axis A, and at an angle of up to about 90° relative to longitudinal axis A, but other angles are contemplated. As illustrated in FIG. 7, the auxiliary inflatable side portion 32 can have a generically spherical central portion 33 which is connected to a proximal shaft 41, as well a distal shaft 43. The components of the auxiliary inflatable side portion 32 may be sized appropriately, as will be readily apparent to those skilled in the art. The central spherical portion 33 can be provided with a suitable inflated diameter D. The diameter D can vary according to various factors known to those skilled in the art. According to a non-limiting, exemplary embodiment, the diameter D can be on the order of a few millimeters. For example, the diameter D is on the order of about 1.5–6.0mm and, preferably, on the order of about 3.34–3.36mm.

FIG. 8 illustrates an alternative auxiliary inflatable side portion construction 132. According to this embodiment, the central portion 133 of the auxiliary inflatable side portion 132 extends in a generally equidistant manner from the longitudinal axis A, and at an angle of up to about 90° relative to longitudinal axis A, but other angles are contemplated. As illustrated in FIG. 8, the balloon 132 comprises a generally elliptical central portion 133, as well as a proximal shaft portion 141, and distal shaft 143 connected thereto. As with the previous embodiment, the various components of the balloon 132 may be sized as appropriate within appropriate dimensional ranges, as determined by those skilled in the art. The elliptical central section 133 of the balloon 132 is provided with major and minor diameters,  $D_1$  and  $D_2$ , respectively, as illustrated in FIG. 7. According to non-limiting exemplary embodiments, the elliptical central section may be shaped such that the ratio  $D_2/D_1$  is on the order of about 0.8. According to further exemplary non-limiting embodiments, the major diameter  $D_1$  is preferably on the order of about 3.65–3.85mm and can range from 1.5–6mm, while

the minor diameter  $D_2$  is smaller than  $D_1$  and is preferably on the order of about 2.9–3.1mm.

FIG.9 illustrates yet a further embodiment of auxiliary inflatable side portion 232 of bifurcated balloon 26 constructed according to the principles of the present invention. According to this embodiment, the central portion 232 is offset relative to the longitudinal axis A and preferably extends toward and/or into the branch vessel 44. The central portion 232 may extend at an angle of up to about 90° relative to longitudinal axis A, but other angles are contemplated. As illustrated in FIG. 9, the auxiliary inflatable side portion 232 of balloon 26 comprises an offset central bulbous or generally spherical portion 233, with a proximal shaft portion 241 and distal shaft portion 243 connected thereto via a proximal transition section 241<sub>T</sub> and distal transition 243<sub>T</sub>, respectively. As with the previous embodiments, the various components of the auxiliary inflatable side portion 232 of balloon 26 can be sized as appropriate, and as readily determined by those skilled in the art. According to exemplary, non-limiting embodiments, the auxiliary inflatable side portion 232 of balloon 26 can be configured such that the central offset portion 233 is provided with a radius of curvature R which is on the order of about .50–3.0mm.

FIG. 10 illustrates yet another alternative embodiment for an auxiliary inflatable side portion 332 of bifurcated balloon member 26. According to this embodiment, the central portion 332 is offset relative to the longitudinal axis A and preferably extends toward and/or into the branch vessel 44 (not shown). The central portion 332 may extend at an angle of up to about 90° relative to longitudinal axis A, but other angles are contemplated. As shown in FIG. 10, the auxiliary inflatable side portion 332 is configured such that it comprises a generally offset elliptical and cylindrical central section 333, with proximal shaft portions 341 and distal shaft portions 343 connected thereto via proximal transition section 341<sub>T</sub> and distal transition portion 343<sub>T</sub>, respectively. The offset central section 333 is preferably configured such that it comprised a first diameter  $D_1$  and second diameter  $D_2$  wherein  $D_1$  and  $D_2$  have different values ( $D_1 \neq D_2$ ). The dimensions of the various constituent components of the auxiliary inflatable side portion 332 can be determined by those skilled in the art. According to exemplary non-limiting embodiments, the auxiliary inflatable side portion 332 can be configured such that it is provided with first and second diameters

such that the ratio  $D_2/D_1$  is on the order of about 0.25–4.0mm. According to further, non-limiting examples, the auxiliary inflatable side portion 332 can be configured such that it is provided with a first diameter  $D_1$  which has dimensions on the order of about 1.5–6.0mm and, preferably about 2.7–2.9mm, and a second diameter  $D_2$  which has dimensions on the order of about 1.5–6.0mm, and preferably about 2.1–2.3mm.

FIG. 11 illustrates yet another alternative embodiment of an auxiliary inflatable side portion 432 of bifurcated balloon 26. According to this embodiment, the central portion 432 is offset relative to the longitudinal axis A and preferably extends toward and/or into the branch vessel 44 (not shown). The central portion 432 may extend at an angle of up to about 90° relative to longitudinal axis A, but other angles are contemplated. The auxiliary inflatable side portion 432 is configured such that it comprises an offset generally cylindrical central section 433 having a proximal shaft portion 441 and a distal shaft portion 443 connected thereto via proximal transition shaft portion 441<sub>T</sub> and distal transition portion 443<sub>T</sub>, respectively. The various constituent components of the balloon 432 can be configured with relative dimensions which can be ascertained by those skilled in the art. According to exemplary, non-limiting examples, the balloon 432 can be configured such that it is provided with an offset generally cylindrical central section 433 having a diameter D which is on the order of about 1.5–6.0mm.

FIGS. 12-15 illustrate further alternative embodiments of the present invention which can be utilized in the treatment of branch arteries, including incorporation into stent-delivery systems of the type previously described. The balloons depicted in the embodiments of FIGS. 12-15 can be referred to as “herniated” balloon configurations that function in a manner similar to the embodiments described above. The herniated balloon configuration is characterized by having a generally cylindrical shape in an unexpanded configuration, and a generally cylindrical shape with a generally hemispherical appendage that inflates outwardly relative to the longitudinal axis of the balloon toward the branch artery in an expanded state or configuration. This protrusion can be referred to as a herniation, bulge, protrusion, or extension. The particular shape, size, and configuration of the balloon and the herniations illustrated herein are exemplary, and may be modified from that explicitly shown and described. The expandable herniation, bulge, protrusion, or extension can be expandable towards

the entrance of side branch (e.g. - 44, FIG.3) over a suitable dimension, such as 1–4mm.

The embodiments of the balloons depicted in FIGS. 12-15 can be utilized in a manner similar to that which has been described in connection with previously illustrated embodiments (see, e.g. – FIGS. 1-6).

With regard to the embodiments depicted in FIGS. 12-15, it should be understood that the herniated balloon constructions depicted therein can be utilized as one or more of the first and second inflatable portions of a bifurcated balloon (e.g. 26, FIGS. 1-6). Alternatively, the herniated balloon constructions can be utilized in place of a bifurcated-type balloon. In other words, the herniated balloon can be utilized by itself instead of a balloon construction which relies upon distinct first and second inflatable portions. An exemplary embodiment of a herniated balloon catheter 526 is illustrated in FIG. 12. In the illustrated embodiment, the herniated balloon catheter 526 comprises an elongated inflatable portion 528 and a herniation, bulge, protrusion, or extension 532 therewith. In the embodiment of FIG. 12 the balloon catheter further includes a lumen 534 which can serve to communicate pressure for inflation of the balloon catheter 526, and provide a passage way for a guide wire, etc.

The particular configuration and dimensions of the balloon catheter 526 can vary according to a number of factors. For purposes of illustration only, certain suitable, but non-limiting, dimensions of various components of the balloon catheter 526 will now be described. The balloon catheter 526 can be provided with a length dimension  $L_1$  which is about 4–100mm. The balloon can be provided with an outside diameter  $OD_1$  which is on the order of about 1–10mm, and the herniation 532 can be provided with a radius of curvature  $R_1$  which is about 0.5–3mm.

FIG. 13 illustrates a portion 526' of a herniated balloon catheter, which includes a herniation 533'. According to further non-limiting examples, the balloon portion 526' can be provided with the following suitable dimensions: outside diameter  $OD_2$  of 1–10mm; a length dimension  $L_2$  of about 4–100mm; a wall thickness dimension  $T_2$  of about 0.003–0.005mm and a radius of curvature  $R_2$  of the herniated portion 533' of about 0.05–3mm.

Another alternative herniated balloon construction is shown in FIG. 14, where the herniated balloon portion 526'' is provided with an alternatively configured herniation 533''. Illustrative and non-limiting examples of suitable dimensions according to this embodiment include: an outside diameter  $OD_3$  (FIG. 15) of about 1–10mm; a length dimension  $L_3$  of about 4–100mm; a height dimensions H of the herniation 533'' of about 1–6mm; and a radius of curvature  $R_3$  of the herniation 533'' of about 0.5–3mm; and a wall thickness of the herniated balloon catheter portion 526'' of about 0.01mm.

Although the herniation 533, 533', and 533'' of the embodiments illustrated in FIGS. 12–15 are shown as being centrally located on the herniated balloon catheter 526 or herniated balloon catheter portions 526', 526'', it should be noted that the herniation 533, 533', and/or 533'' maybe located at any desired position along the length of the balloon. For example, once associated with a stent, it can preferably be placed such that it corresponds to the location along the middle 1/3 of the stent.

The balloon 526, 526', and/or 526'' can be constructed of any suitable material such as those previously disclosed herein. In addition, the balloon 526, 526', and/or 526'' can be constructed of a composite material. Suitable materials include a combination of elastomeric and semi to non-compliant materials such as: urethane; silicone; nylon; latex; (elastomeric) polyethylene hytrel pebax polyaryletherketone; polyoxymethylene; polyamide; polyester thermoplastic polyetheretherketone; and polypropylene (semi non-compliant). The balloon 526, 526', and/or 526'' can be also be constructed by combining the above-disclosed materials with woven textile materials such as Kevlar, silk, cotton, wool, etc. This can be accomplished by winding or weaving a textile material onto a rod that has the shape of the desired herniated balloon. The polymer component of the composite is then extruded or dip-coated over the rod. This composite structure is then cured, heat set, or adhesively fused together. The rod is then removed and the remaining shape comprises the herniated balloon 526, 526', and/or 526''.

The herniation 533, 533', and/or 533'' can be provided by adding an appendage to a conventional balloon by using a molded collar or adhesively attaching an object to the surface of the balloon, or by using a mound of adhesive to create the herniation.

The balloon 526, 526', and/or 526'' can be constructed by molding three small balloons and attaching them in tandem. The central balloon comprising the desired shape of the herniation. These balloons would share a common inflation port. When the balloons are inflated, the center balloon expands in the desired manner to form the herniation.

According to further aspects of the present invention, more than two inflatable portions or more than two balloons may be utilized. For example, as shown in FIGS. 16-18, the balloon may include a plurality of second inflatable portions. In this regard, a user may be able to treat multiple bifurcations with a single device. Such a configuration, may also eliminate the need for a secondary positioning lumen (side sheath 20) and reduce the profile of the system. As shown in FIGS. 16-17, in one exemplary embodiment, balloon 626 includes four inflatable portions 662 positioned radially around a first inflatable portion 660. In an alternate embodiment, shown in FIG. 18, a plurality of inflatable balloon portions 662 are spaced longitudinally adjacent one side of first inflatable portion 660.

Referring to FIG. 19, a cross-sectional view of an alternative embodiment of a balloon 772 is shown. Balloon 772 includes a main inflatable portion 774 and further extends into secondary inflatable portion 776. Lumen 778 can be of various diameters, compliances, and materials to control the timing and size of the secondary expandable portion 776 upon inflation. In one embodiment, second expandable portion 776 may deploy subsequent to main expandable portion 774. Such a time delay may be achieved, for example, using a smaller diameter inflation lumen leading up to secondary expandable portion 776 since the inflation fluid travels along path 779 first through the main expandable portion 774 and then on to secondary expandable portion 776. In this regard, delivery system 770, may permit sequential deployment of two expandable portions using a single inflation port.

Referring to FIG. 20, a cross-sectional view of an alternative embodiment of a balloon 880 is shown in an expanded state. Balloon 880 comprises a main inflatable portion 882 and an auxiliary inflatable portion 884. Main expandable portion 882 has an indentation or cavity configured and dimensioned to receive a portion of auxiliary expandable portion 884 when balloon 880 is inflated. For example, as shown in FIG. 20 auxiliary inflatable portion is generally spherically shaped and when inflated,

cavity 886 is aligned and positioned to accommodate a portion of the spherical shape. In this regard, when balloon 880 is inflated, the inflated balloon has the approximate peripheral shape of a cylinder with a hemispherical protrusion. In use, the auxiliary expandable portion 884 is configured to deploy or extend outwardly deployable elements of a stent into a bifurcation. In operation, when both expandable portions are inflated, such a balloon configuration allows for varying expansion capabilities and preferably prevents the region of a stent adjacent second inflatable portion 884 from over expanding into the bifurcated region. As a result, the possibility of causing trauma to the vessel is preferably limited.

While the invention has been described in conjunction with specific embodiments and examples thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art upon reading the present disclosure. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. Furthermore, features of each embodiment can be used in whole or in part in other embodiments.

**WHAT IS CLAIMED IS:**

1. An apparatus for treatment of a bifurcation of a body lumen, the bifurcation comprising a main vessel and a branch vessel, the apparatus comprising:

a bifurcated balloon comprising a first branch portion and a second branch portion; the second branch portion comprising an inflatable portion adapted to extend toward the branch vessel, the bifurcated balloon further comprising a proximal shaft portion and a distal shaft portion connected to the inflatable portion of the second branch portion;

wherein the first branch portion and the second branch portion each have a longitudinal axis, the longitudinal axis of the first branch portion is substantially parallel to the longitudinal axis of the second branch portion.

2. The apparatus of claim 1, wherein the inflatable portion of the second branch portion is generally spherical.

3. The apparatus of claim 1, wherein the inflatable portion of the second branch portion is generally elliptical and comprises a major and minor axis.

4. The apparatus of claim 1, wherein the inflatable portion of the second branch portion is generally in the form of an offset bulbous shape.

5. The apparatus of claim 1, wherein the inflatable portion of the second branch portion is generally in the form of an offset elliptical cylinder.

6. The apparatus of claim 1, wherein the inflatable portion of the second branch portion is generally in the form of an offset cylinder.

7. The apparatus of claim 1, wherein the second branch comprises a plurality of inflatable portions.

8. The apparatus of claim 7, wherein said plurality comprises more than two inflatable portions.

9. The apparatus of claim 8, wherein the inflatable portions are circumferentially spaced about the first branch portion.

10. The apparatus of claim 8, wherein the inflatable portions are longitudinally spaced along the first branch portion.

11. The apparatus of claim 1, wherein the first and second branches share a common inflation lumen.

12. A system for treatment of a bifurcated body lumen, the system comprising:

a catheter for insertion into said body lumen, the catheter having a bifurcated distal end comprising first and second branches; and

a bifurcated balloon positioned on one of said first and second branches;

the bifurcated balloon having a first balloon branch and a second balloon branch, the first balloon branch including a first inflatable portion and the second balloon branch including a second inflatable portion, and

wherein the first inflatable portion has a generally cylindrical shape when inflated and the second inflatable portion has a generally offset bulbous shape when inflated.

13. The system of claim 12, further comprising:

a stent mounted on the bifurcated balloon, the stent including a side branch access hole.

14. The system of claim 13, wherein the stent includes an extendible branch portion configured and dimensioned to extend into a branch vessel upon expansion of the stent.

15. A method of treating a bifurcation of a body lumen, the bifurcation comprising a main vessel and a branch vessel, the method comprising:

(i) introducing a bifurcated balloon and stent assembly into the main vessel, the bifurcated balloon comprising at least one inflatable portion;

(ii) positioning the assembly at the bifurcation;

(iii) inflating the bifurcated balloon thereby expanding the inflatable portion and deploying the stent in the main vessel and outwardly toward the branch vessel.

16. The method of claims 15, wherein the bifurcated balloon comprises a first branch and a second branch, the at least one inflatable portion being disposed on the second branch of the bifurcated balloon.

17. A balloon catheter, comprising:

a catheter having a distal end, a proximal end and an inflation lumen;

a balloon formed on the distal end of the catheter, the balloon being in fluid communication with the inflation lumen and being capable of being expanded from an unexpanded configuration to an expanded configuration, wherein the balloon is generally cylindrical in the unexpanded configuration and has a herniation in the expanded configuration.

18. A herniated balloon catheter, comprising:

a balloon constructed from a composite material and including a woven material formed with a herniation, wherein the balloon has a herniation in the expanded condition.

19. The herniated balloon catheter according to claim 18, wherein the herniation is formed by balloon material.

20. The herniated balloon according to claim 18, wherein the herniation is formed by adhesive attached to the balloon.

21. A stent delivery system, comprising:

a catheter having a balloon with a herniation; and

a stent having a side opening including an outwardly expandable portion, the stent being disposed on the balloon with the stent side opening aligned with the herniation, whereby upon expansion of the balloon the herniation expands causing the outwardly expandable portion of the stent to extend toward a branch vessel.

22. A method for treating a bifurcated blood vessel, the method comprising:

introducing into the blood vessel a catheter having a distal end, a proximal end, a guide wire lumen that is adapted to receive a guide wire, and a balloon having a distal end and a proximal end, the balloon being disposed near the distal end of the catheter, the balloon having a protrusion at a location between the distal end and

proximal end of the balloon, and a stent having a side opening through a wall thereof, the stent being disposed over the balloon, wherein the protrusion of the balloon is positioned adjacent the side opening;

positioning the catheter at a bifurcation by aligning the stent side opening with a side branch blood vessel; and

expanding the balloon so as to deploy the stent such that the side opening of the stent is aligned with the opening of the bifurcated vessel.

23. The method according to claim 22, wherein the stent further comprises an outwardly expandable portion disposed around any portion of the side opening wherein the expanding balloon deploys the outwardly expandable portion of the stent toward a side branch blood vessel.

24. A system for treatment of a bifurcation of a body lumen, the bifurcation comprising a main vessel and a branch vessel, the system comprising:

a catheter for insertion into said body lumen, the catheter having a distal end, a proximal end, and an inflation lumen;

a balloon in fluid communication with the inflation lumen, the balloon having a first branch and a second branch, the second branch comprising an inflatable portion having a generally bulbous shape adapted to extend toward the branch vessel upon inflation; and

a stent disposed on the balloon, the stent having an opening including an outwardly expandable portion, the opening aligned with the inflatable portion, whereby expansion of the inflatable portion causes the outwardly expandable portion to extend toward the branch vessel.

25. The system of claim 24, wherein the first branch and the second branch each have a longitudinal axis, the longitudinal axis of the first branch portion being substantially parallel to the longitudinal axis of the second branch portion.

26. The system of claim 24, wherein the inflatable portion is generally in the form of an elliptical cylinder.

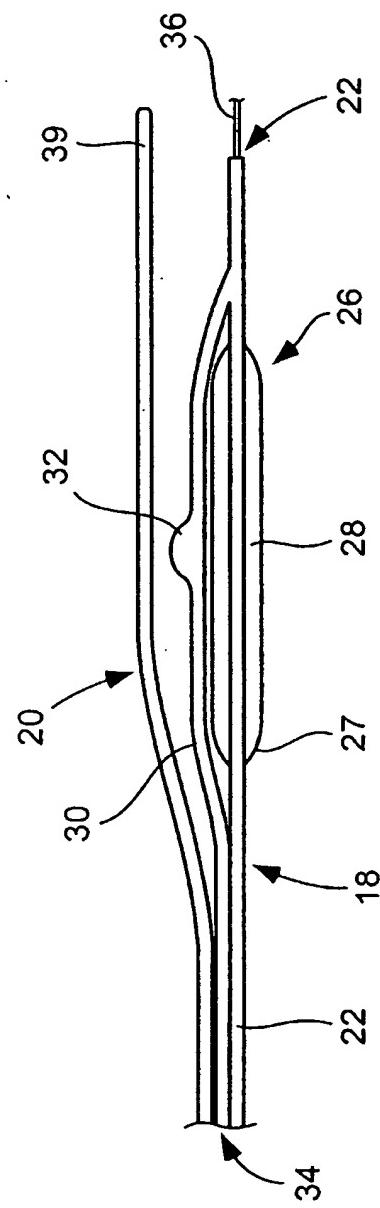
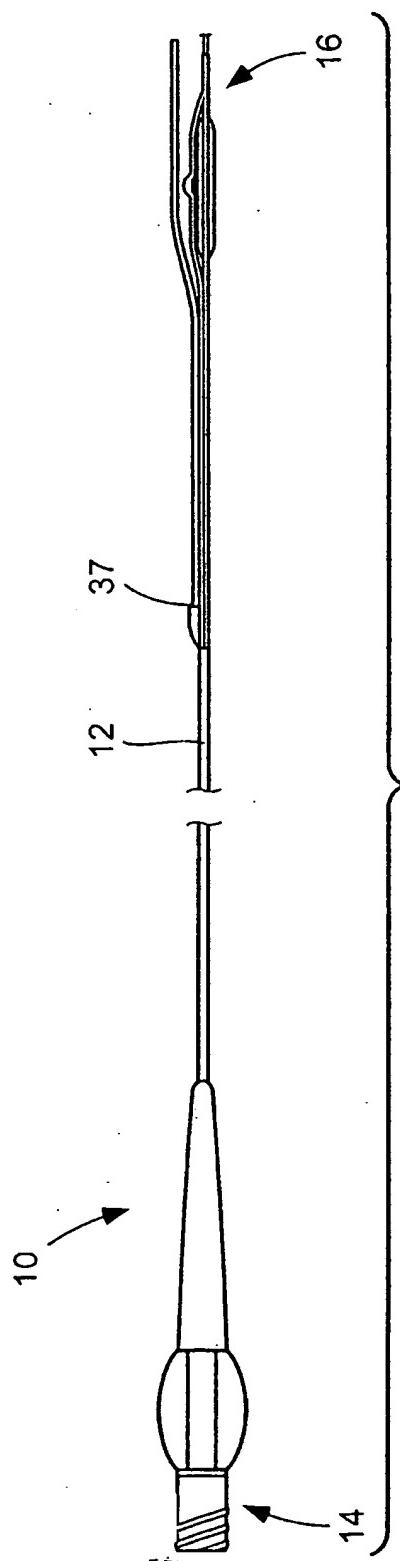
27. The system of claim 24, wherein the inflatable portion is generally in the form of an offset cylinder.

<sup>23</sup>

28. The system of claim 24, wherein the inflatable portion inflatable portion is generally in the form of an offset bulbous portion.

29. The system of claim 24, wherein the second branch portion comprises a plurality of inflatable portions.

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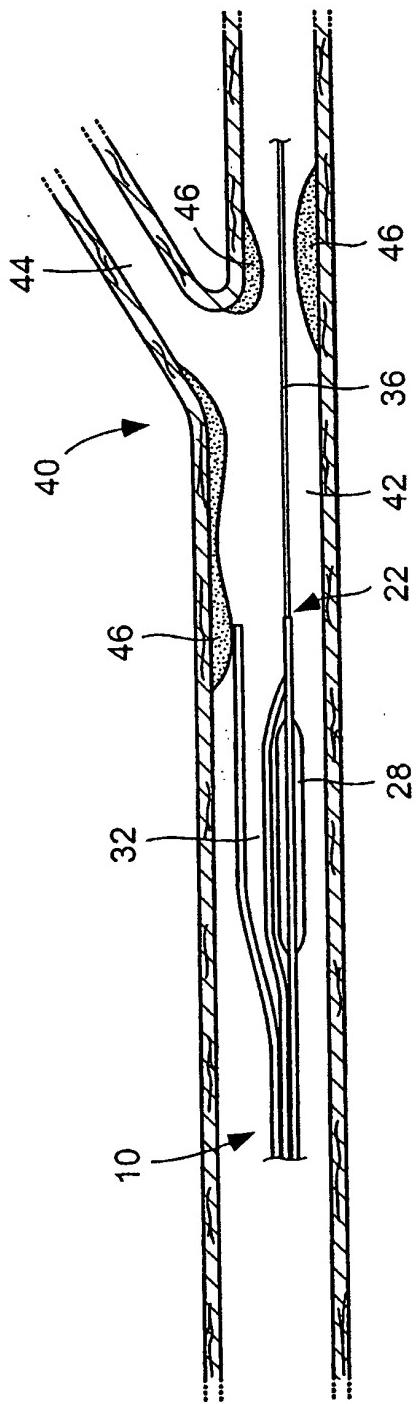


FIG. 3

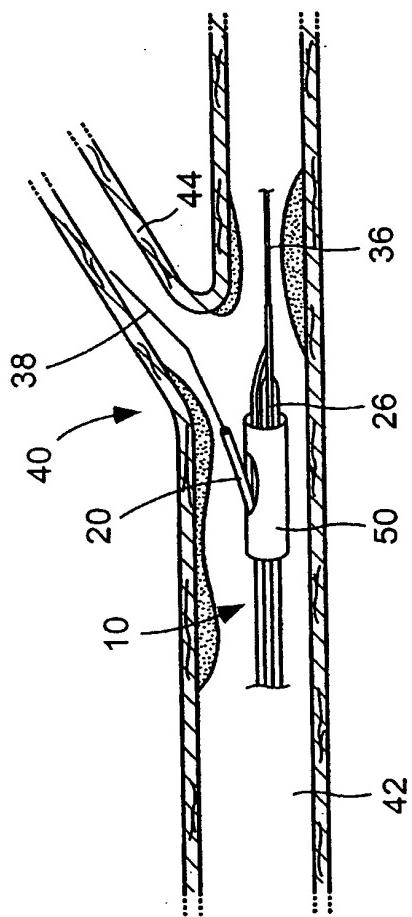
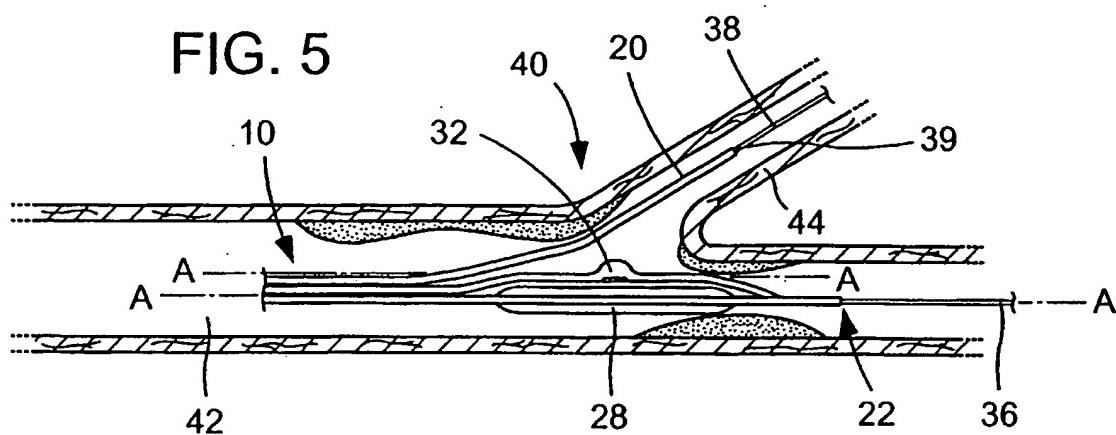
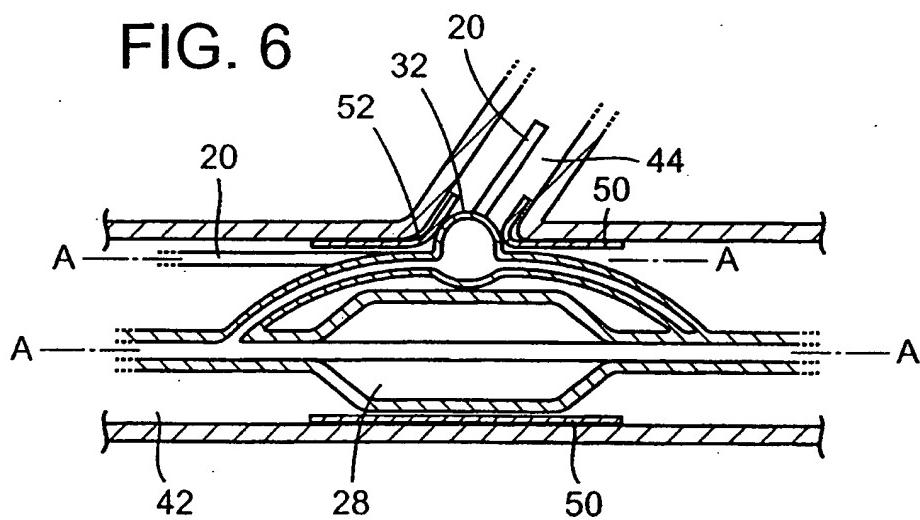
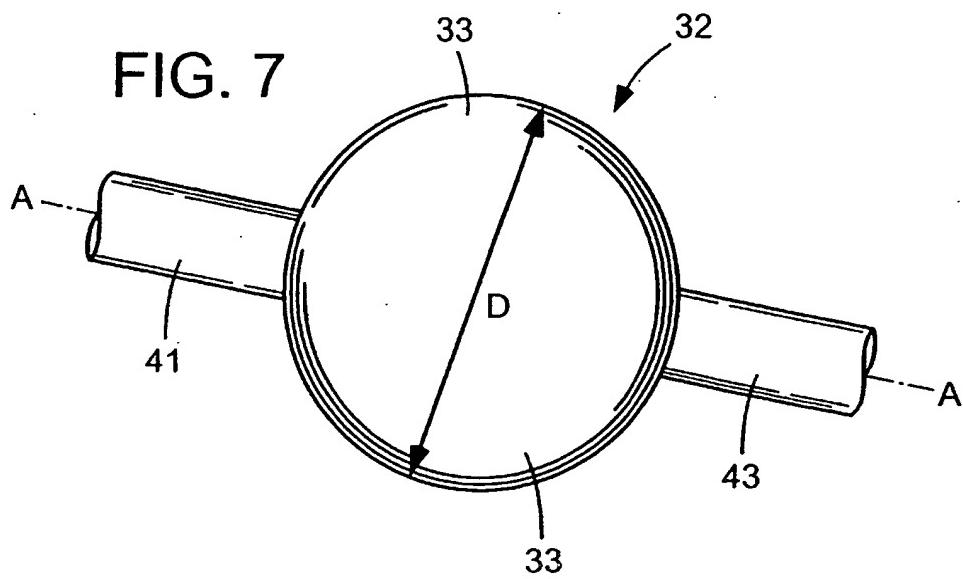


FIG. 4

3/10

**FIG. 5****FIG. 6****FIG. 7**

4/10

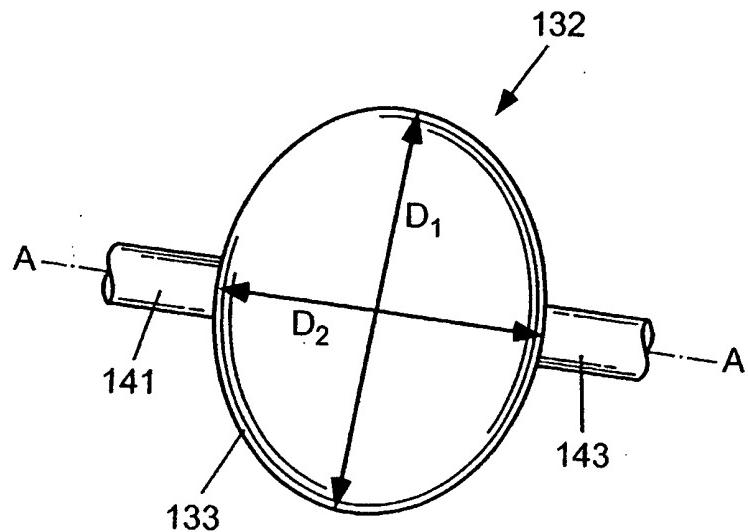


FIG. 8

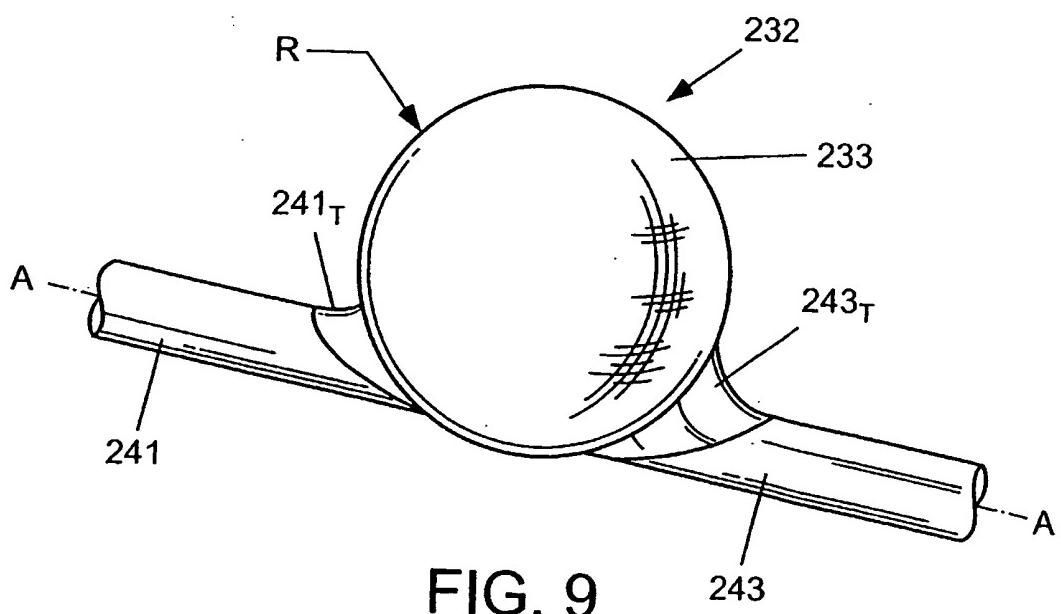


FIG. 9

5/10

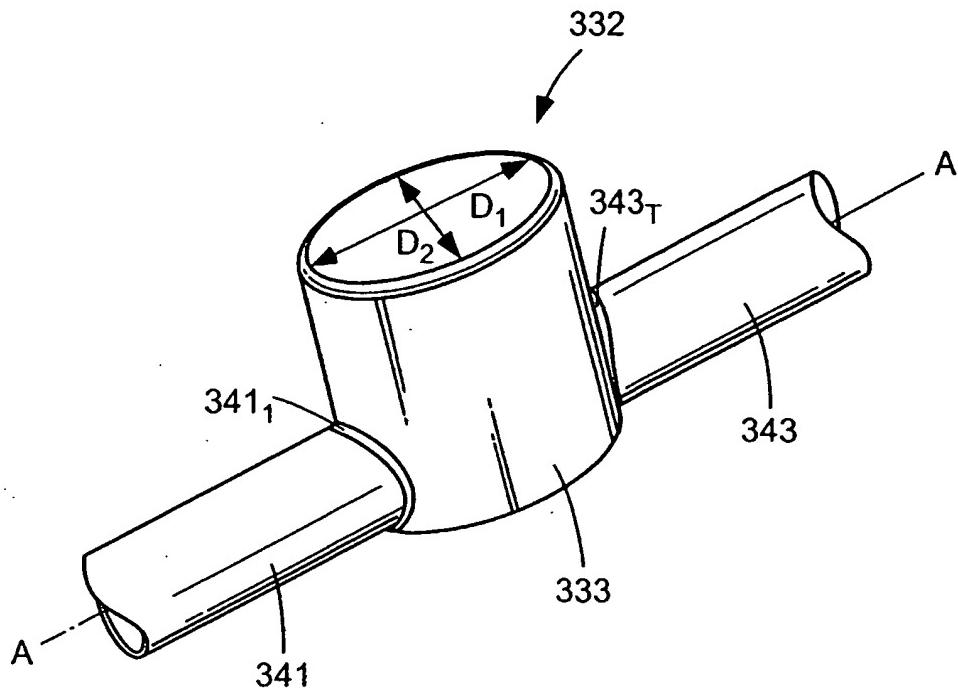


FIG. 10

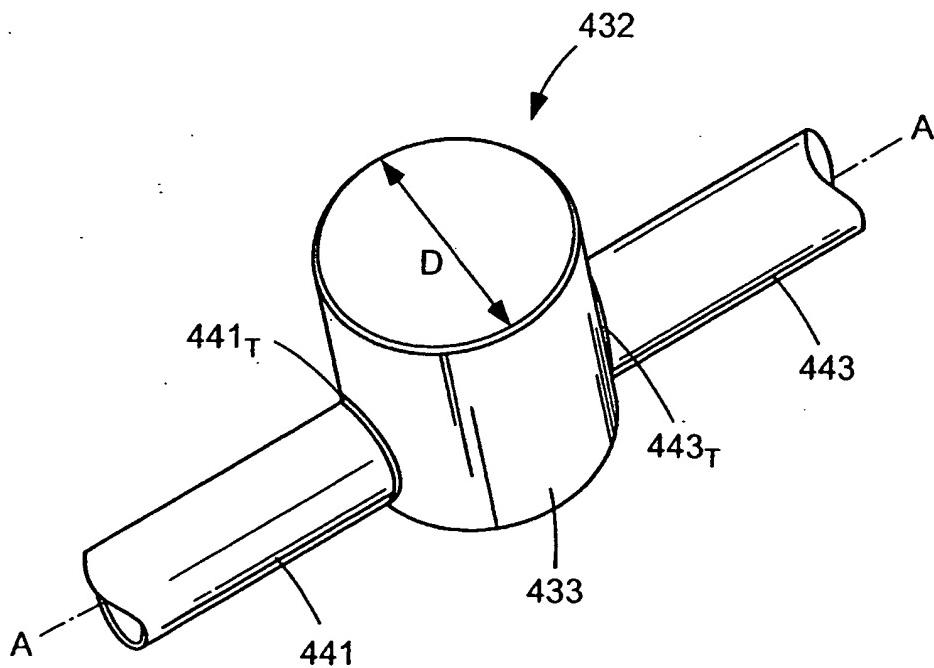
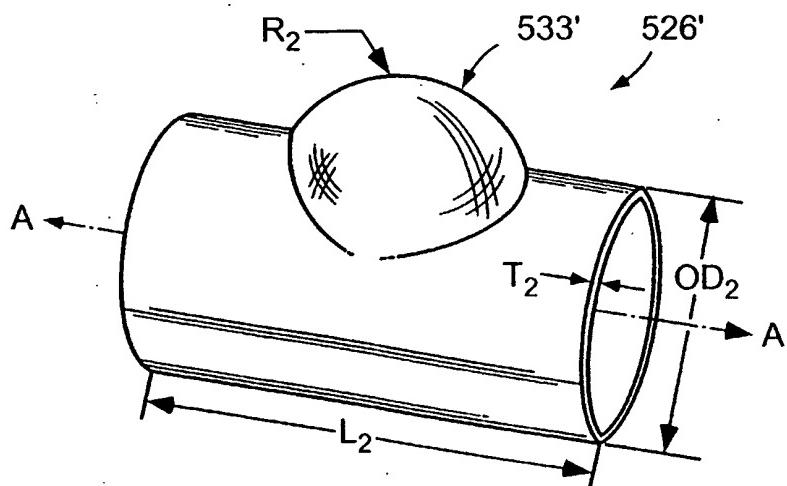
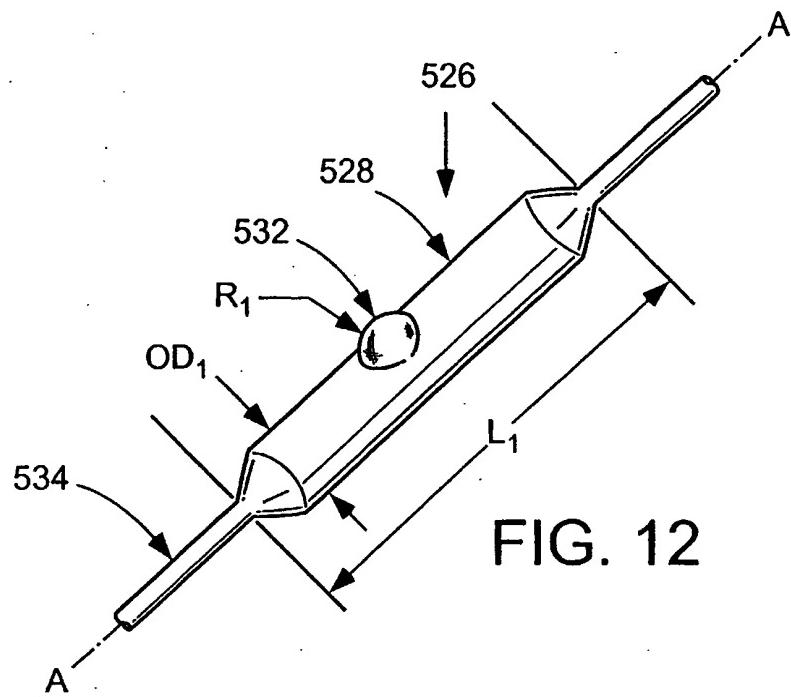


FIG. 11

6/10



7/10

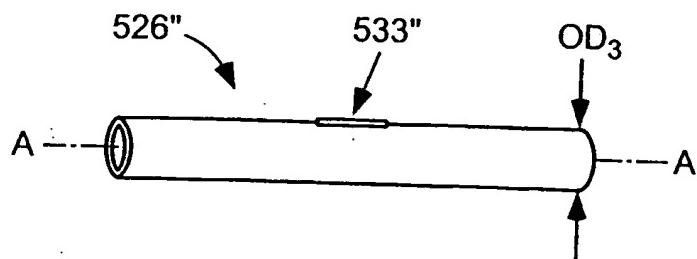
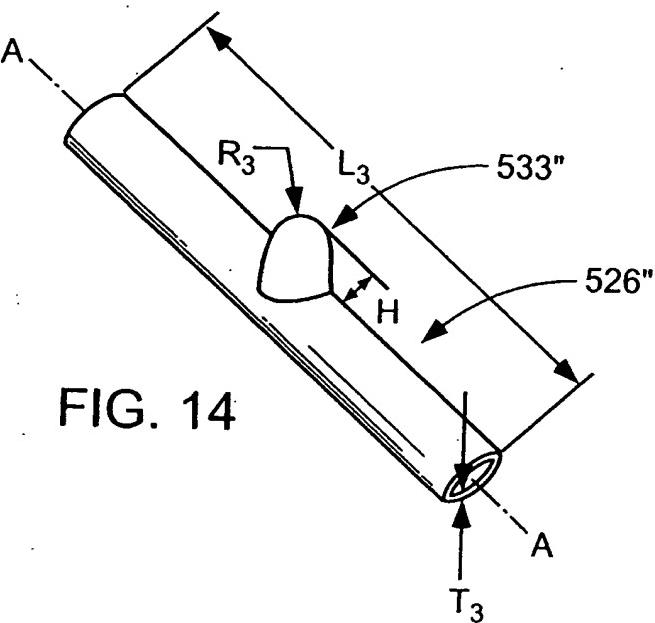


FIG. 15

8/10

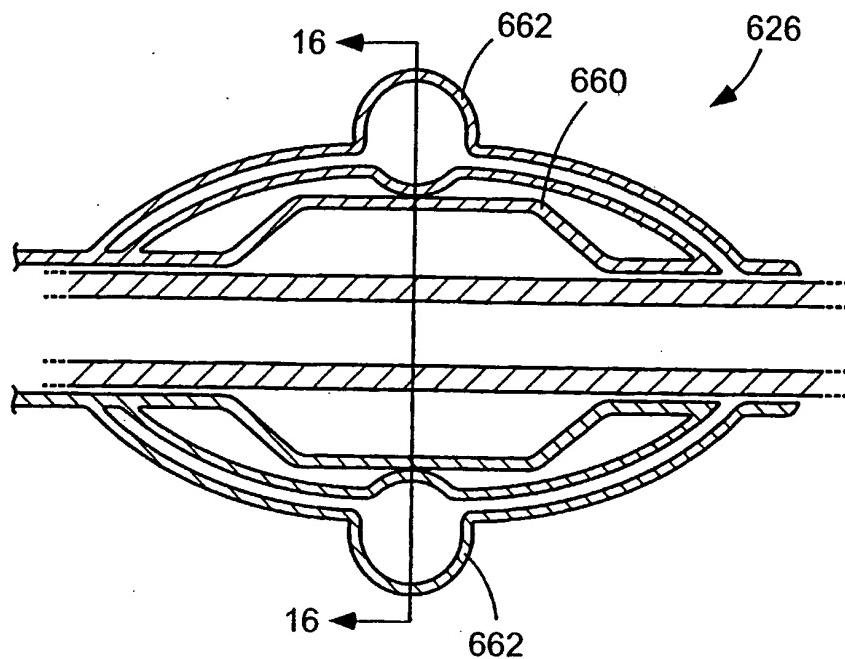


FIG. 16

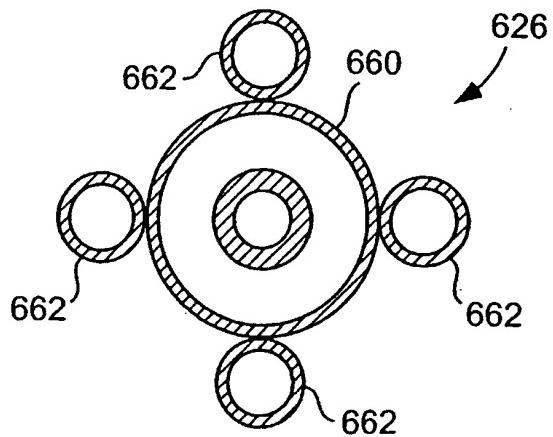


FIG. 17

9/10

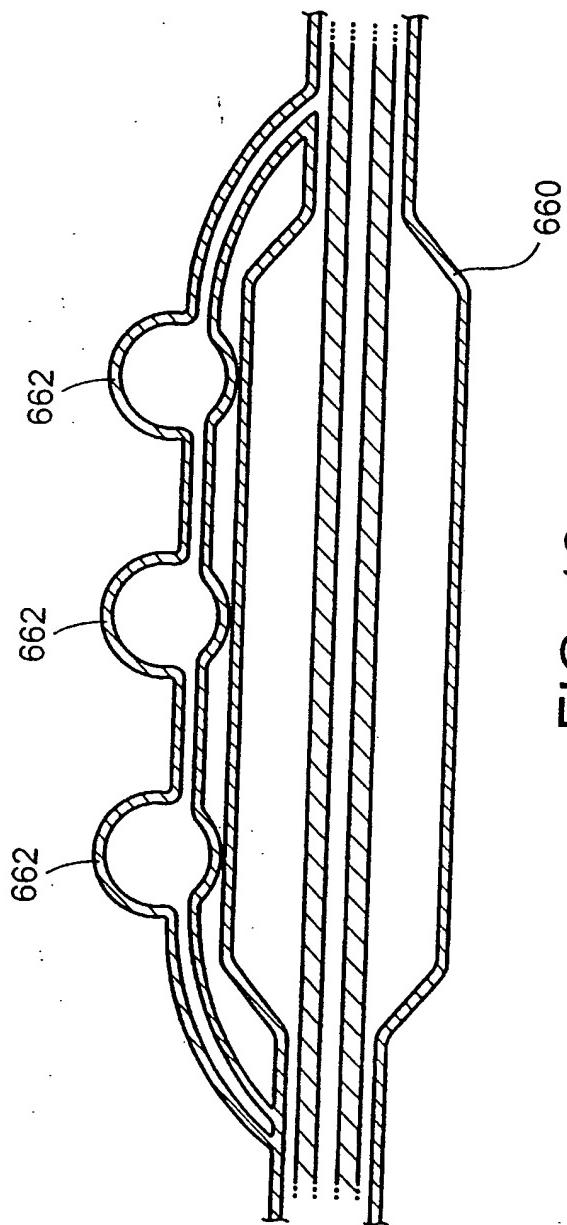


FIG. 18

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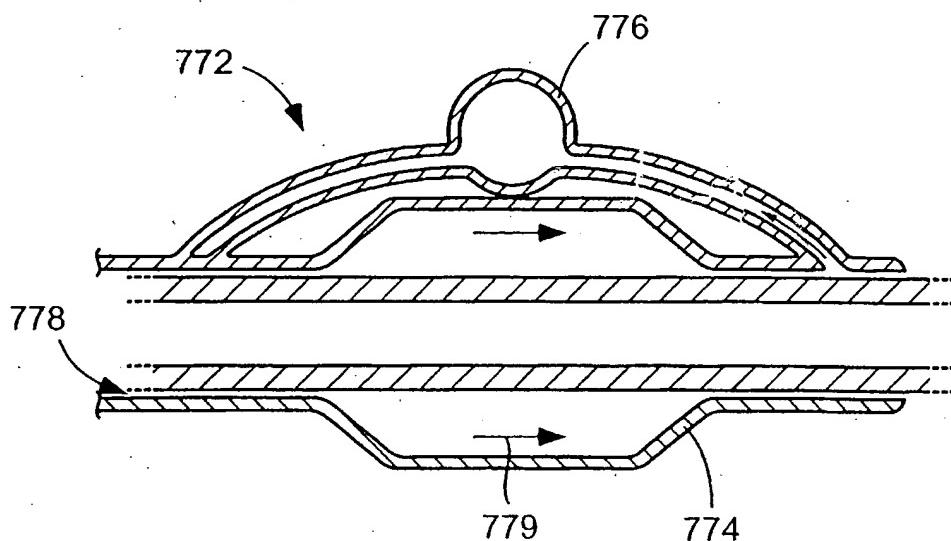


FIG. 19

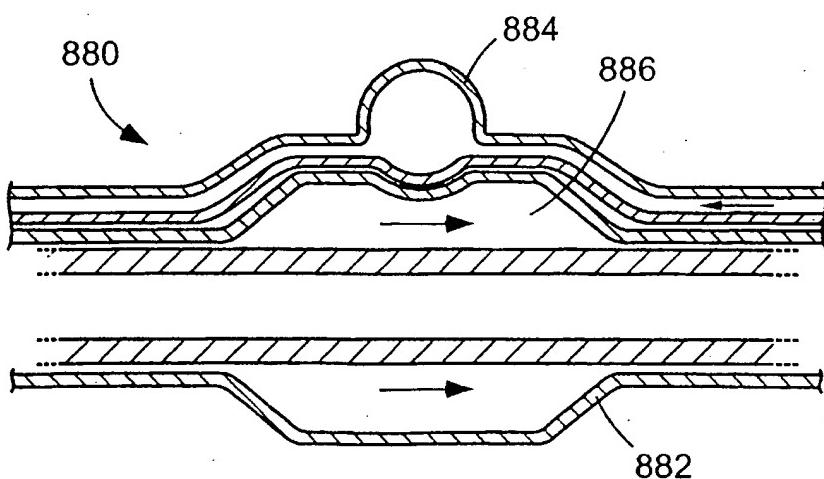


FIG. 20

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